



November 22, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-0521, Menthol in Cigarettes, Tobacco Products; Request for Comments

To Whom It May Concern:

The American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO) appreciate the opportunity to provide input on the U.S. Food and Drug Administration's (FDA's) Advance Notice of Proposed Rulemaking regarding menthol in cigarettes. As the nation's leading scientific and professional organizations representing cancer researchers and oncology care professionals, the AACR and ASCO strongly support the development of evidence-based tobacco control policies aimed at reducing the burden of death and disease caused by tobacco use, which is the leading preventable cause of death in the United States and around the world. Consistent with the scientific evidence demonstrating that menthol cigarettes have an adverse impact on public health, the AACR and ASCO urge the FDA to ban the addition of menthol as a characterizing flavor to cigarettes and other combustible tobacco products. We also recommend that the FDA evaluate the public health impact of tobacco products containing menthol and other flavorants at sub-characterizing levels and the impact that banning these flavorants altogether would have on public health.

As the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) stated in its comprehensive review of the issue, menthol cigarettes have an adverse impact on public health in the United States. Moreover, multiple lines of investigation support a role for menthol cigarettes in increasing experimentation and progression to regular smoking. Youth who initiated smoking with menthol cigarettes are more likely to become daily, regular, or established smokers than those who initiated with non-menthol cigarettes, and adolescent menthol cigarette smokers have a higher prevalence of nicotine dependence and more severe nicotine addiction than those who smoke non-menthol cigarettes.

Moreover, the danger of menthol-flavored cigarettes falls disproportionately on African Americans. For example, African Americans are more likely to smoke menthol cigarettes, and African-American menthol smokers are also less likely to quit smoking successfully than are non-menthol smokers. Banning menthol flavoring would be an important step toward reducing tobacco-associated harm to this population and would curtail a longstanding tobacco industry marketing approach targeting African Americans, including youth.

In the pages that follow we have provided additional input on the questions posed in the FDA's request for comments on menthol in cigarettes.

A. Tobacco Product Standards

1. Should FDA consider establishing a tobacco product standard for menthol in menthol cigarettes? If so, what allowable level of menthol (e.g., maximum or minimum) would be appropriate for the protection of the public health?

The AACR and ASCO urge FDA to establish a tobacco product standard for menthol in cigarettes. Specifically, and in light of the evidence showing that menthol cigarettes have an adverse impact on public health, increase experimentation and progression to regular smoking, and disproportionately affect African-Americans, we strongly recommend that the FDA ban the addition of menthol to cigarettes and other combustible tobacco products as a characterizing flavor.

Our organizations are also concerned that the addition of menthol and other flavorants to combustible tobacco products at levels below characterizing levels could facilitate smoking initiation (particularly among youth), dependence, and addiction. Indeed, the TPSAC review cites at least one report showing that the addition of menthol at concentrations below those used in non-menthol cigarettes (and undetectable by taste and aroma) is likely to make smoke smoother and less harsh. We strongly recommend that the FDA evaluate the public health impact of cigarettes and other combustible products containing menthol at sub-characterizing levels and the impact that banning these constituents would have on public health.

2. Rather than a tobacco product standard for menthol in menthol cigarettes, should FDA consider a tobacco product standard for any additive, constituent, artificial or natural flavor, or other ingredient that produces a characterizing flavor of menthol in the tobacco product or its smoke?

The AACR and ASCO support a ban on the inclusion of any additive, constituent, artificial or natural flavor, or other ingredient that produces a characterizing flavor of menthol in combustible tobacco products or their smoke or any ingredients that, like menthol, reduce the harshness and irritation of smoke and that may increase smoking initiation, dependence, and addiction.

3. If a tobacco product standard for menthol in menthol cigarettes were to be established, should FDA consider issuing regulations to address menthol in other tobacco products besides cigarettes? If so, what other tobacco products with menthol should be regulated: All tobacco products, just all combusted tobacco products, or some other category or group of tobacco products? If not, what distinctions should be made between products?

The AACR and ASCO support a ban on the addition of any ingredient that produces a characterizing flavor of menthol in combustible tobacco products or their smoke including in cigarettes, cigars, and roll-your-own, pipe, and hookah tobacco.

4. If a product standard prohibiting or limiting menthol were to be established, what length of time should manufacturers be provided to achieve compliance with the standard? If a product standard prohibiting or limiting menthol were to be established, would a stepped approach in which the level of menthol was gradually reduced be appropriate for the protection of the public health?

The AACR and ASCO recommend an immediate ban on the addition of ingredients that produce a characterizing flavor of menthol to combustible tobacco products or their smoke. An immediate ban on flavors would improve public health more quickly than a stepped approach to reducing the level of menthol in these products. The sooner we can reduce smoking initiation and the development of dependence in adolescents, the greater the probability of reducing tobacco-related morbidity and mortality in the future.

5. If a product standard limiting menthol were to be established, are there alternatives that could be substituted by manufacturers to maintain the effect or appeal of menthol to menthol cigarette smokers and potential initiators? If so, what are these substitutes? Should they be regulated if menthol is regulated; and if so, how should they be regulated? If not, what distinctions should be made between menthol and potential substitutes?

In its report, TPSAC notes that tobacco companies have explored adding chemicals with menthol-like cooling effects to cigarettes. The AACR and ASCO support a ban on the addition of any ingredient that imparts a menthol-like cooling effect to combustible tobacco products or that otherwise reduces the harshness and irritation of tobacco smoke.

B. Sale and Distribution Restrictions

1. Should FDA consider establishing restrictions on the sale and/or distribution of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?

The evidence evaluated by TPSAC demonstrates that the availability of menthol cigarettes has an adverse impact on public health by increasing the numbers of smokers with resulting premature death and avoidable morbidity. In light of these data, TPSAC stated that removal of menthol cigarettes from the marketplace would benefit public health in the

United States. To achieve this goal, we urge FDA to implement a full ban, including prohibiting the manufacture, sale, and distribution, of cigarettes and other combustible tobacco products containing menthol as a characterizing flavor.

2. Should FDA consider establishing restrictions on the advertising and promotion of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?

The manufacture, sale, and distribution of combustible tobacco products containing menthol as a characterizing flavor should be banned, obviating the need for advertising bans on these products. The FDA should, however, also consider the implications of implementing a ban on products intended to be used in conjunction with non-mentholated cigarettes in order to impart the flavor of menthol to the product or otherwise reduce the harshness or irritation associated with tobacco smoke. The sale and marketing of such products could make it possible to evade the ban on mentholated products and undermine FDA efforts to safeguard public health.

C. Other Actions and Considerations

1. Are there other tobacco product standards, regulatory, or other actions that FDA could implement that would more effectively reduce the harms caused by menthol cigarette smoking and better protect the public health than the tobacco product standards or regulatory actions discussed in the preceding questions?

The most effective action the FDA could take to reduce the harms caused by menthol cigarettes is to implement a full ban on cigarettes and other combustible tobacco products containing menthol as a characterizing flavor.

2. Is compliance with the tobacco product standard or other regulatory action you identified technically achievable?

Compliance with a ban on the addition of menthol as a characterizing flavor to cigarettes and other combustible tobacco products is technically achievable. Menthol is an additive to tobacco and, therefore, it is possible to limit the amount of menthol added to tobacco products to levels below those known to produce characterizing flavors. The FDA has successfully banned the addition of other characterizing flavors to cigarettes and roll-your-own tobacco, demonstrating the feasibility of a similar ban on menthol.

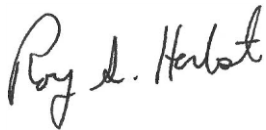
4. What additional information and research beyond that described in the evaluation is there on the potential impact of sale and distribution restrictions of menthol cigarettes on specific subpopulations, such as those based on racial, ethnic, socioeconomic status, and sexuality/gender identity?

As we discussed above, menthol cigarette smoking disproportionately harms African-Americans and youths. African Americans are especially likely to smoke menthol cigarettes and African-American menthol smokers are less likely than non-menthol smokers to quit

successfully. At the same time, African Americans are more likely to develop lung cancer, more likely to be diagnosed with the disease at an advanced stage, less likely to seek treatment, and more likely to die of lung cancer than their white counterparts. Banning the addition of menthol as a characterizing flavor to cigarettes and other combustible tobacco products would be an important step forward in protecting the health of these populations.

Thank you for very much for considering our input on this important issue. If the AACR or ASCO can provide any additional information or assistance to the FDA, please do not hesitate to contact Jennifer A. Hobin, Ph.D., Director of Government Relations for AACR at (202) 898-6499 or jennifer.hobin@aacr.org or Courtney Tyne, M.P.H., Health Policy Manager for ASCO at (571) 483-1667 or courtney.tyne@asco.org.

Sincerely,



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